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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,897	07/30/2003	Itaru Sakou	1448.1042	6247

21171 7590 07/11/2006

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EXAMINER
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LIN, JERRY

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/629,897	SAKOU, ITARU	
	Examiner	Art Unit	
	Jerry Lin	1631	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 25, 26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 25, 26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1 page</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I, Species A (claims 1-3, 25, 26, 28, and 29) in the reply filed on April 3, 2006 is acknowledged.

***Status of the Claims***

Claims 1-3, 25, 26, 28, and 29 are under examination.

Claims 4-11 are withdrawn as being directed to a unelected species.

Claims 12-24, 27, and 30 are cancelled (directed to a unelected invention).

***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 25, 26, 28, and 29, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps required to determine the expression sites of the first gene based on distance. Calculating the distance between genes on a genome sequence does not in itself

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determine the expression sites of a gene. Further processing or data manipulation is required in order to use the distance between genes to find the expression site of a gene.

5. Claim 1-3, 25, 26, 28, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "gene expression site" is used in claims 1-3, 25, 26, and 29. However it is unclear what the applicants intend the term to mean. The term is not explicitly defined in the specification. One interpretation of this term is that the "gene expression site" is the portion of the gene that is transcribed, also known as a "transcription unit." Another interpretation of this term is that it refers to where the gene expressed in an organism. For purposes of this office action, the former will be used.

***Claim Rejections - 35 USC § 112, 1st Paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3, 25, 26, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement in light of Cohen et al. (Nature Genetics, October 2000, Volume 26, pages 183-186). The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification teaches that the determination of the gene expression site is based on the distance between the unknown gene and known genes (page 5, lines 9-14). Furthermore, the specification teaches that if the distance meets a threshold distance from a known gene, the expression site of the unknown gene may be predicted (pages 17-18), since it would share the expression site of the known gene (i.e., coexpressed). However, it is unclear how the distance between a known gene and an unknown gene will necessarily result the prediction of the expression site of the unknown gene. For example, Cohen et al. teach the correlation between the distance between genes and the likelihood those genes will be coexpressed. Although Cohen et al. do teach that the closer ORFs are together, the more likely they will be coexpressed, Cohen et al. also states that "the distance between ORFs is not in itself a predictive of increased correlation." (page 184, right column, 2<sup>nd</sup> full paragraph). In other words, although the distance between genes may show a trend of coexpression, that trend does not predict whether a gene is coexpressed with a known gene. Since the trend does not necessarily lead to a prediction of gene expression sites, one of skill in the art would have to perform undue experimentation in order to determine the gene expression sites of an unknown gene. Thus without further guidance from the specification or method steps, one of skill in the art would not be enabled to use the invention as claimed to predict expression sites without undue experimentation.

***Claim Rejections - 35 USC § 101***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-3, 25, 26, 28, and 29 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claims 1-3, the instant claims are drawn to a mathematical algorithm. A mathematical algorithm is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or a useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if

the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include any tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a computational means of determining gene expression sites. However, as claimed, the method does not include a real world result. For example, method, as claimed, may take entirely within the confines of a computer or the human mind without any communication to the outside world. Thus the instant claims do not include any tangible result.

Regarding claims 25, 26, 28, and 29, consideration of the "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, also clarifies that claiming such non-statutory subject matter on a computer medium or in software does not prevent this rejection.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 25, 26, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Salgado et al. (PNAS, June 6, 2000, Volume 97, Number 12)

The instant claims are drawn to a method of determining where genes are expressed on a genome by calculating the distance between genes and determining the expression site based on that distance.

Regarding claims 1, 25, and 28, Salgado et al. teach method of calculating the distance between genes (page 6653, left column), wherein the expression site of the first gene is unknown (page 6656) and determining the functional class and transcription unit (expression site) from the distance (page 6655). Salgado et al. teach performing this method on a computer program, which would require a computer apparatus (page 6652, right column, first paragraph under data preparation).

Regarding claim 2, 26, and 29, Salgado et al. teach a method of determining the expression site of a gene by using a predetermined distance relationship among a plurality of genes (page 6655-6656). Salgado et al. teach performing this method on a computer program, which would require a computer apparatus (page 6652, right column, first paragraph under data preparation).

Regarding claim 3, Salgado et al. teach a method of calculating the distance between genes (abstract). When calculating the distance between genes, the number of base pairs between the closest points on the genes is calculated. Thus if two genes are transcribed in opposite directions, the two closes points on the genes are the start positions. Since Salgado et al. teach calculating the distance between genes, Salgado et al.'s method also teaches calculating the distance between the two genes by determining the number of base pairs between the start positions of each gene.



***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'MBorin', is written over the printed name of the examiner.

JL